

REMARKS

Claims 1-21 are pending in the instant application. Claims 1-15 are rejected, and claims 16-21 are withdrawn from consideration. As a preliminary matter, the Examiner makes the Restriction Requirement final.

Rejection under 35 U.S.C. 112, second paragraph

The Examiner rejects claims 1 and 7 as allegedly unclear because the definitions of "lamellar bodies" and "linear macromolecules" are allegedly unclear. The terms are expressly defined in paragraphs [0022] and [0033] of the specification, respectively. Applicants submit that these definitions in the instant specification are clear. Moreover, the term "lamellar body" is a specific, well defined scientific term.

Rejection under 35 U.S.C. 102

A. WO 01/72277

The Examiner rejects all of the pending claims 1-15 as anticipated by WO 01/72277.

B. Schmitz, *Journal of Lipid Research* (1991) or Post, *Experimental Lung Research* (1982) or Nemechek (1997) or King *et al.*, *Am J Physiol Lung Cell Mol Physiol*. (2002)

The Examiner rejects claims 1, 6 and 7 as allegedly anticipated by Schmitz, *Journal of Lipid Research* (1991) or Post, *Experimental Lung Research* (1982) or Nemechek (1997) or King *et al.*, *Am J Physiol Lung Cell Mol Physiol*. (2002).

C. Applicant's Response

Applicants submit that an inventive aspect of the present invention relates to the recognition that the composition is effective in modifying linear macromolecules, which are gel forming, such as mucin. This in turn indicates potential therapeutic uses in a wide range of disease states such as cystic fibrosis and otitis media.

Applicants submit that the prior art does not teach or suggest that the specific composition of the present invention would demonstrate significant effect on linear macromolecules as is recited in all the claims (1 and 7 explicitly and by way of dependency the

remaining claims of 1-15). In particular, Nemecek teaches that bovine lung surfactant does not necessarily correlate with the specific composition being claimed and would not lead one of ordinary skill in the art to believe that lamellar bodies can modify linear biological macromolecules. Furthermore, the prior art does not teach the amounts of phospholipid mixtures necessary to obtain the structures as recited in the instant claims. One of ordinary skill in the art finds no teaching or suggestion in the prior art to utilize the composition of the present claims, especially of dependent claims 2-6 and 8-15.

Rejection under 35 U.S.C. 103

A. King *et al.*, *Am J Physiol Lung Cell Mol Physiol*. (2002)

The Examiner rejects pending claims 1-4, 6-10 and 12-15 as allegedly unpatentable over King *et al.*, *Am J Physiol Lung Cell Mol Physiol*. (2002). The Examiner admits that King *et al.* may not teach the amounts of PC, PI, PS,PG, sphingomyelin and cholesterol recited in the claims in weight percentages. However, the Examiner says that the purpose of King *et al.* is to study the viscosities of various synthetic surfactant compositions so that it would have been obvious to one of ordinary skill in the art to vary the amount of the individual components to obtain the best possible combination resembling natural surfactant. The Examiner acknowledges that King *et al.* teach that sphingomyelin is present in natural surfactants at about 2%.

B. Nemecek (1997), or Nemecek (1997) in view of WO 01/72277, or Nemecek (1997) in view of King *et al.*, *Am J Physiol Lung Cell Mol Physiol*. (2002) and WO 01/72277

The Examiner rejects all of the pending claims 1-15 as allegedly unpatentable over Nemecek (1997), or Nemecek (1997) in view of WO 01/72277, or Nemecek (1997) in view of King *et al.*, *Am J Physiol Lung Cell Mol Physiol*. (2002) and WO 01/72277. The Examiner admits that Nemecek does not teach the amounts of PC, PI, PS,PG, sphingomyelin and cholesterol recited in the claims. However, the Examiner says that it would have been obvious to one of ordinary skill in the art to increase the amount of sphingomyelin since it provides softness and flexibility to lamellar bodies.

C. Applicant's Response1. *The Examiner has not set forth a proper prima facie case of obviousness.*

Applicants reiterate as set forth, *supra*, that an inventive aspect of the present invention relates to the recognition that the composition is effective in modifying linear macromolecules, which are gel forming, such as mucin. This in turn indicates potential therapeutic uses in a wide range of disease states such as cystic fibrosis and otitis media.

Applicants submit that the prior art does not suggest that the specific composition of the present invention would demonstrate significant effect on linear macromolecules as is recited in all the claims (1 and 7 explicitly and by way of dependency the remaining claims of 1-15). In particular, Nemechek teaches that bovine lung surfactant does not necessarily correlate with the specific composition being claimed and would not lead one of ordinary skill in the art to believe that lamellar bodies can modify linear biological macromolecules. There simply would be no reasonable expectation of success in such an endeavor. Furthermore, the prior art does not suggest the amounts of phospholipid mixtures necessary to obtain the structures as recited in the instant claims. One of ordinary skill in the art would find no suggestion in the prior art to utilize the composition of the present claims, especially of dependent claims 2-6 and 8-15. Moreover, there would be no reasonable expectation of succeeding in modifying linear macrotubules even if the modification were made.

2. *The presently claimed compositions provide unexpectedly superior results and unexpectedly superior properties.*

Applicant respectfully reminds the Examiner that it is a fundamental principle of the patent law that subject matter which might otherwise be unpatentable is rendered patentable when it provides unexpectedly superior results. That is "secondary considerations" such as unexpectedly superior results or properties may be used to rebut a *prima facie* case of obviousness. In order to further indicate the surprising effectiveness of the presently claimed compositions, Applicant provides details of experimental work showing the effectiveness of the compositions, submitted herewith as Exhibit A. Applicant submits Exhibit A in order to clearly demonstrate the surprising effectiveness of the claimed compositions on linear biological

macromolecules. The composition according to the instant invention is termed LMS-611 throughout Exhibit A. The Figures and Tables referenced are provided at the end of the text describing the experimental procedures and results.

Rejection under the judicially created doctrine of obviousness type double patenting

The Examiner rejects all of the pending claims 1-15 as allegedly patentably indistinct from claims 1-4, 8, 11-13, and 15 of copending United States Serial No. 10/678,743. According to the Examiner, the two sets of claims describe lamellar bodies having overlapping percentages of individual components. At this time, Applicant submits a willingness to consider filing a Terminal Disclaimer once otherwise patentable subject matter is identified. This is believed sufficient since the rejection is "provisional."

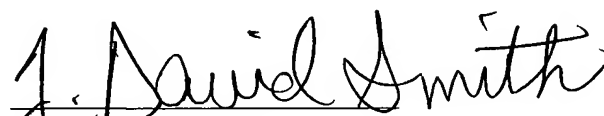
FEES

No additional fees are believed necessary in connection with the present submission; however, should this be in error, authorization is hereby given to charge Deposit Account No. 11-1153 for any underpayment or to credit any overage.

CONCLUSION

It is believed that all of the claims are patentable and early notification as such is earnestly solicited. If any issues may be resolved by way of telephone, the Examiner is invited to call the undersigned at the telephone number indicated below.

Respectfully submitted,


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